EXHIBIT A

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

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IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	: : :	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
--	:	Judge Joseph R. Goodwin
This Document Applies To All Actions	:	
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PLAINTIFFS' FIRST REQUESTS FOR ADMISSION TO DEFENDANTS

To: William M. Gage
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Pursuant to Rule 36 of the Federal Rules of Civil Procedure, the matters set forth in the following Requests for Admissions will be deemed admitted unless, within 30 days after service of the request, Defendants serve upon Plaintiffs a written answer or objection addressed to the matter, signed on behalf of Defendants or by Defendants' attorney. If objection is made to any request for admission, the grounds therefore must be stated. If a matter is not admitted, then the answer must specifically deny it or set forth in detail the reasons why Defendants cannot truthfully admit or deny the matter. A denial shall fairly respond to the substance of the requested admission; and, when good faith requires that Defendants qualify their answer or deny only a part of the matter of which an admission is requested, Defendants shall specify so much of it as is true and qualify or deny the rest. Defendants may not give lack of information or knowledge as a reason for failure to admit or deny unless it states that reasonable inquiry has been made and that the information known or readily obtainable by Defendants is insufficient to enable it to admit or deny.

Definitions

1. "Defendants", "Ethicon, Inc." ("Ethicon"), "Johnson & Johnson Inc." ("J&J"), "you" or "your" refers to, without limitation, Ethicon, Inc., Johnson & Johnson Inc., and all business entities with which it is or has been affiliated, together with any predecessor, successor, parent, or subsidiary entity as well as any officer, director, employee, attorney, agent, or representative of any such other business entity previously described herein and specifically includes but is not limited to Johnson & Johnson, J&J International, Ethicon, Inc., Ethicon SARL, Ethicon SAS, Ethicon LLC, Johnson and Johnson Medical LTD, MD&D Global Services, LLC, Ethicon LTD and Johnson and Johnson Medical GMBH.

2. All definitions and rules of instructions set forth in Fed. Rule Civ. P. 30(b)(6) shall apply to all requests for information herein. To the extent a term commonly in use in the medical device industry is not defined herein, it shall be understood to be consistent with the meaning commonly ascribed to that term in the medical device industry.

3. "Concerning" means referring to, describing, evidencing, or constituting. *See* LR Civ. P 26.2(c)(7).

4. "Document" is synonymous in meaning and equal in scope to the usage of this term in Rule 34(a) of the Federal Rules of Civil Procedure and expressly includes writings, drawings, graphs, charts, photographs, sound recordings, images, and other data or data compilations stored in any medium from which information can be obtained either directly or, if necessary, after translation by you into a reasonably usable form. A draft or non-identical copy is a separate document. *See* LR Civ. P. 26.2(c)(2); *see also* FR Civ. P 34(a).

5. "TVT IFU" means the TVT Instructions for Use (IFU) including all the approved and in-use IFUs identified by defendants from lines 17 through 30 in the IFU Index and Production Bates Range Chart Produced to Plaintiffs on 05/24/13.

6. "Patient Brochure" or "patient brochures" means the brochures identified TVT/SUI Patient Brochures Index and Production Bates Range Chart Produced to Plaintiffs on 08/26/13.

7. "TVT" or "TVT device" means the TVT Tension Free Vaginal Tape System (Retropubic) cleared by the FDA on or about January 28, 1998, which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI). The term "TVT" also includes any kits or tools designed to be sold with the TVT including, but not limited to the TVT-AA and TVT-D.

8. "TVT Products" includes the TVT, TVT-O, TVT-A, TVT-E and TVT-S as defined below, and includes both laser cut and mechanically cut versions.

9. "TVT-O" means the TVT-Obturator kit first marketed on or about December 08, 2003 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

10. "TVT-A" means the TVT-Abbrevo Tension Free Vaginal Tape kit first marketed on or about July 1, 2010 which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

11. "TVT-E" means the TVT-Exact kit first marketed on or about March 16, 2010, which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

12. "TVT-S" means the TVT-Secur kit first marketed on or about November 28, 2005

which was developed, designed, distributed, licensed, manufactured, marketed or sold for the treatment of Stress Urinary Incontinence (SUI).

13. "TVT mesh" or "Prolene* mesh" means the surgical mesh used in the TVT constructed of knitted filaments of extruded polypropylene identical in composition to Prolene* Polypropylene Suture, Nonabsorbable Surgical Sutures, U.S.P. (ETHICON, INC.).

14. "Relevant Time Period" means the time period from when you first developed, designed, distributed, licensed, manufactured, marketed or sold TVT to the present.

REQUESTS FOR ADMISSION

Pursuant to Federal Rule of Civil Procedure 36, Plaintiffs request that Defendants respond in the time and manner required by law to the following requests for admission:

1. Admit that you never completed a controlled study involving live women with the actual TVT device (not a prototype) prior to marketing and selling the TVT in the U.S.

2. Admit that you never completed a randomized controlled trial with the actual TVT device (not a prototype) prior to marketing and selling the TVT in the U.S.

3. Admit that the mesh used in the TVT is and has always been the Prolene* 6 mil that was first used in hernia mesh sold by defendants in approximately1974, as illustrated in ETH.MESH.01816990, attached hereto.

4. Admit that the mesh used in the TVT is, and has always been, the mesh with the specifications identified in the document titled Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

5. Admit that the mesh used in the TVT is, and always has been, the same "Old Construction Prolene* Mesh" as defined in the Material Specifications for TVT Prolene*, ETH.MESH.06136033, attached hereto.

6. Admit that the mesh used in the TVT is, and has always been, manufactured using 6 mil clear monofilament or 6 mil dyed monofilament polypropylene, as described in the Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

7. Admit that the mesh used in the TVT weighs 102 grams per meters squared as stated in Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

8. Admit that the average pores in the TVT mesh marketed and sold in the U.S are, and have always been, less than 1 mm in diameter in all directions when sold.

9. Admit that the specifications for the TVT mesh marketed and sold in the U.S. do not require the pores of the mesh to be greater than 1 mm in diameter in all directions when sold.

10. Admit that the TVT mesh marketed and sold in the United States is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

11. Admit that the TVT mesh is not "lightweight mesh" as defined by: Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

12. Admit that the TVT-O has always been manufactured and sold in the U.S. with "Old Construction Prolene* Mesh" as defined in the Material Specification for TVT Prolene, ETH.MESH.06136033, attached hereto.

13. Admit that the mesh used in the TVT-O is and has always been, manufactured using 6 mil clear monofilament or 6 mil dyed monofilament polypropylene, as described in the Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto

14. Admit that the mesh used in the TVT-O weighs 102 grams per meters squared as stated in Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

15. Admit that the pores in the TVT-O mesh marketed and sold in the U.S are, and have always been, less than 1 mm in diameter in all directions when sold.

16. Admit that the specifications for the TVT-O mesh marketed and sold in the U.S. do not require the pores of the mesh to be greater than 1 mm in diameter in all directions when sold.

17. Admit that the mesh used in the TVT-O marketed and sold in the U.S. is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

18. Admit that the mesh used in the TVT-O is not "lightweight mesh" as defined by: Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

19. Admit that, with the exception of the ETHISORB®/PDS film ends, the TVT-S uses the same "Old Construction Prolene* Mesh" as defined in the Material Specifications for TVT Prolene, ETH.MESH.06136033, attached hereto.

20. Admit that, with the exception of the ETHISORB/PDS film ends, the mesh used in the TVT-S is and has always been manufactured using 6 mil clear monofilament or 6 mil dyed monofilament polypropylene, as described in the Material Specifications for TVT Prolene*, ETH.MESH 06136033, attached hereto.

21. Admit that, with the exception of the ETHISORB/PDS film ends, the Prolene* mesh used in the TVT-S weighs 102 grams per meters squared as stated in Material Specifications for TVT Prolene, ETH.MESH 06136033, attached hereto.

22. Admit that the pores in the TVT-S mesh marketed and sold in the U.S are, and have always been, less than 1 mm in diameter in all directions when sold.

23. Admit that the specifications for the TVT-S mesh marketed and sold in the U.S. do not require the pores of the mesh to be greater than 1 mm in diameter in all directions when sold.

24. Admit that the TVT-S mesh marketed and sold in the United States is "heavyweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

25. Admit that the TVT-S mesh is not "lightweight mesh" as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002), attached hereto.

26. Admit that the mesh used in the TVT, TVT-O, and TVT-S devices is identical, with the exception of the ETHISORB®/PDS film ends on the TVT-S device.

27. Admit that the mesh used in the TVT device is identical to that used in the TVT-O device.

28. Admit that the intravaginal slingplasy ("IVS") device used in the Medscand Scandinavian Multicenter Study, the study report signed by Margareta Eriksson on October 17, 1997 (at ETH.MESH 08476340), and submitted to the FDA with the 510(k) for the TVT, was not identical to the TVT device that was launched and sold in the U.S. starting in 1998.

29. Admit that the mesh used to treat patients in the IVS device that was used in the Medscand Multicenter Scandinavian Study, signed by Margareta Eriksson on October 17, 1997 (at ETH.MESH 08476340), and submitted to the FDA with the 510(k) for the TVT, was not

identical to the TVT mesh in the TVT device that was launched and sold in the U.S. in starting in 1998.

30. Admit that the IVS device used in the study published with Nilsson, Ulmsten and others as authors entitled, Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary, *Internationa*l, *Urogynecology Journal*, Vol. 12: (2001), was not identical to the TVT device marketed and sold in the U.S. starting in 1998.

31. Admit that the IVS device used in the study published with Nilsson, Ulmsten and others as authors entitled, Long-term Results of the Tension-Free Vaginal Tape (TVT) Procedure for Surgical Treatment of Female Stress Urinary, *Internationa*l, *Urogynecology Journal*, Vol. 12: (2001), was not identical to the TVT device marketed and sold in the U.S. starting in 1998.

32. Admit that you paid Medscand Medical AB $400,000.00 or more for submitting to J&J International Clinical Trials that were “acceptable” to J&J International pursuant to Section 3.6, as specified in Exhibit C to the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB at ETH.MESH.09746948.

33. Admit that Professor Ulmsten was an investigator in the clinical trial and ultimately an author of the published paper resulting from the clinical trial that resulted in your payment of $400,000.00 to Medscand Medical AB for an “acceptable” Clinical Trial pursuant to Section 3.6 of the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB at ETH.MESH.0974694.

34. Admit that Professor Nilsson was an investigator in the clinical trial and ultimately an author of the published paper resulting from the clinical trial that resulted in your

payment of $400,000 or more to Medscand Medical AB for an “acceptable” Clinical Trial pursuant to Section 3.6 of the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB.

35. Admit that you paid Professor Ulmsten over $2 million as a paid consultant during the years 1997 to 2004.

36. Admit that you paid Professor Ulmsten over $3 million as a paid consultant during the years 1997 to 2004.

37. Admit that you paid Professor Ulmsten over $5 million as a paid consultant during the years 1997 to 2004.

38. Admit that you have paid Professor Nilsson over $1 million as a paid consultant.

39. Admit that you have paid Dr. Mickey Karram over $1 million as a paid consultant.

40. Admit that you have paid Dr. Mickey Karram over $2 million as a paid consultant.

41. Admit that you have paid Dr. Paul Henniford over $1 million as a paid consultant.

42. Admit that you have paid Dr. Paul Henniford over $2 million as a paid consultant.

43. Admit that you knew that Professor Ulmsten was a shareholder of Medscand Medical AB at the time you paid Medscand Medical AB $400,000.00 or more for submitting to J&J International Clinical Trials that were “acceptable” to J&J International pursuant to Section 3.6, as specified in Exhibit C to the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical AB.

44. Admit that you have knowledge that Professor Ulmsten received over $5million as a shareholder of Medscand Medical AB when J&J purchased the assets of TVT pursuant to

the Asset Purchase Agreement between Medscand Medical AB and J&J International dated November 15, 1999.

45. Admit that you knew that Professor Ulmsten was a shareholder of Medscand Medical AB when J&J purchased the assets of TVT pursuant to the Asset Purchase Agreement dated November 15, 1999.

46. Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten was your paid consultant.

47. Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Nilsson or any of his studies, the fact that Professor Nilsson was your paid consultant.

48. Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Rezapour or any studies in which he was involved, the fact that Professor Rezapour was your paid consultant.

49. Admit that you never disclosed in any of your TVT marketing materials that include references to Professor Christian Falconer or any studies in which he was involved, the fact that Professor Christian Falconer was your paid consultant.

50. Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Ulmsten or any of his studies, the fact that Professor Ulmsten had a conflict of interest due to his relationship with you.

51. Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Nilsson or any of his studies, the fact that Professor Nilsson has a conflict of interest due to his relationship with you.

52. Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Rezapour or any studies in which he was involved, the fact that Professor Rezapour has a conflict of interest due to his relationship with you.

53. Admit that you have never disclosed in any of your TVT marketing materials that include references to Professor Falconer or any studies in which he was involved, the fact that Professor Falconer has a conflict of interest due to his relationship with you.

54. Admit that in 2009 you instituted a policy that prohibits the funding of studies performed by investigators who have a direct ownership interest in the product being studied titled Johnson & Johnson Worldwide MD&D Policy for Investigator-Initiated Studies (Clinical) attached hereto as ETH.MESH.05347755.

55. Admit that your payment to Medscand Medical AB of $400,000.00 for submitting to J&J International Clinical Trials that were "acceptable" to J&J International pursuant to Section 3.6, as specified in Exhibit C to the License and Supply Agreement dated February 13, 1997, between J&J International and Medscand Medical ABA, would have violated your current policy entitled Johnson & Johnson Worldwide MD&D Policy for Investigator-Initiated Studies, attached hereto, if such policy was in effect at the time of the payment.

56. Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson et al., (2001), Long-term results of the tension-free vaginal tape (TVT) procedure for surgical treatment of female stress urinary incontinence, *Int. Urogynecol J.* 12 [Suppl]:5-8

57. Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson CG, Falconer C, Rezapour M., 7-Year

Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Urinary Incontinence, *Obstet Gynecol* 104:1259-1262.

58. Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson CG, Palva K, Rezapur M, Falconer C., Eleven Years Prospective Follow-up of the Tension-Free Vaginal Tape Procedure for Treatment of Stress Urinary Incontinence, *Int Urogynecol J* (2008) 19:1043-1047.

59. Admit that you provided funding or resources for and/or sponsored the study or analysis reflected in the article published as Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C., Seventeen Years' Follow-up of the Tension-Free Vaginal Tape Procedure for Female Stress Urinary Incontinence. (2013) *Int Urogynecol J* DOI 10.1007/s00192-013-2090-2, attached hereto.

60. Admit that you stated to physicians in your marketing material (*see*, e.g. ETH.MESH 00658058 attached hereto) that the TVT mesh has "large pores".

61. Admit that no testing was performed by you, or on your behalf, to measure or otherwise determine the pore size of the mesh used in the TVT prior to the creation of this multi-district litigation.

62. Admit that no testing was performed by you, or on your behalf, to measure or otherwise determine the elasticity of the Prolene* mesh used in the TVT devices prior to the creation of this multi-district litigation.

63. Admit that no testing in humans was performed by you or on your behalf that proves or otherwise supports the claim in the TVT IFU that "the bi-directional elastic property allows adaptation to various stresses encountered in the body."

64. Admit that the testing you rely on to support your statement in the TVT IFU that "the bi-directional elastic property allows adaptation to various stresses encountered in the body" was not testing performed in women with the TVT device.

65. Admit that you never tested the TVT device in live women to determine whether your statement in the TVT IFU that "the bi-directional elastic property allows adaptation to various stresses encountered in the body" is a true statement with respect to the TVT mesh when implanted in women.

66. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could "rope" and, therefore, become permanently narrowed in width during or after placement by physicians.

67. Admit that you knew about "roping" of the TVT mesh as stated in ETH.MESH. 01809078, attached hereto, at the time the TVT was first marketed and sold in the U.S.

68. Admit that you knew about "roping" of the TVT mesh as stated in ETH.MESH. 01809078, attached hereto, by the end of 2004.

69. Admit that you knew as of May of 2005 that the TVT mesh could rope or, in other words, stretch to the point of being a "string" when used by physicians as reflected in ETH.MESH 00526473 attached hereto.

70. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that reduction in the TVT mesh width due to roping or deconstruction of knit could lead to erosion.

71. Admit that you knew by the end of 2006 that reduction in the TVT mesh width due to roping or deconstruction of knit could lead to erosion as indicated in ETH.MESH .01218019, attached hereto.

72. Admit that TVT mesh can curl and/or rope during or after placement by a physician, leading to increased pressure in a localized point on the urethra and potentially causing retention as described in ETH.MESH 01822361, attached hereto.

73. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could curl and/or rope during or after placement by a physician, which could then cause or contribute to cause retention as described in ETH.MESH 01822361, attached hereto.

74. Admit that you knew as of October of 2006 that the TVT mesh could curl and rope during or after placement by a physician, leading to increased pressure in a localized point on the urethra and potentially causing retention. (*See* ETH.MESH 01822361 attached hereto).

75. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the TVT mesh placement resulted in too much localized pressure on the urethra, the TVT mesh could cause an erosion.

76. Admit that you knew as of October of 2006 that if the TVT mesh placement resulted in too much localized pressure on the urethra, the TVT mesh could cause an erosion.

77. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh might not lay flat under the urethra due to roping and curling.

78. Admit that you knew as of October of 2006 that the TVT mesh might not lay flat under the urethra due to roping and curling as described in ETH.MESH 01822361 attached hereto.

79. Admit that the TVT IFU has never stated to physicians that the TVT mesh may not lay flat under the urethra due to roping or curling.

80. Admit that the TVT IFU has never stated to physicians that if the TVT mesh does not lay flat under the urethra, the TVT mesh may cause or contribute to cause urinary retention.

81. Admit that the TVT IFU has never stated to physicians that the TVT mesh can rope or curl or narrow in width during or after placement in a women's body.

82. Admit that the IFU has never stated to physicians that roping or curling or narrowing of the TVT mesh can cause or contribute to cause erosion.

83. Admit that the TVT patient brochures have never informed or advised patients that the TVT mesh could rope, curl, or narrow in width and, as a result, could cause erosion.

84. Admit that the TVT patient brochures have never informed or advised patients that the TVT mesh could rope, curl, or narrow in width and, as a result, could cause urinary retention.

85. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the pores in the TVT mesh collapsed, erosion could occur.

86. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the pores in the TVT mesh were reduced in size during or after placement, erosion could occur.

87. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that if the pores in the TVT mesh were reduced in size during or after placement, the risk of could be increased.

88. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could become encapsulated, not incorporated, due to a reduction in the pore size, which could lead to erosion.

89. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that the TVT mesh could become encapsulated, not incorporated, due to a reduction in the pore size, which could increase the risk of erosion.

90. Admit that you knew by the end of 2006 that the TVT mesh could become encapsulated, not incorporated, caused by a reduction in the pore size and lead to erosion as indicated in ETH.MESH .01218019, attached hereto.

91. Admit that the TVT IFU has never stated to physicians that a reduction in the pore size in the TVT mesh could lead to erosion.

92. Admit that the TVT IFU has never stated to physicians that a reduction in the pore size in the TVT mesh could increase the risk of erosion.

93. Admit that the TVT IFU has never stated to physicians that the TVT mesh could become encapsulated caused by a reduction in pore size and could cause or contribute to cause erosion as a result.

94. Admit that you knew at the time the TVT was first marketed and sold in the U.S. that rough edges of the TVT mesh could cause pain for patients as indicated in ETH.MESH .01218019, attached hereto.

95. Admit that you knew by the end of 2006 that rough edges of the TVT mesh could cause pain for patients as indicated in ETH.MESH .01218019, attached hereto.

96. Admit that you knew as of January of 2000 that TVT mesh could fray and become narrower in places as a result.

97. Admit that you knew as of January of 2000 that TVT mesh could fray and particles of the mesh could break off and remain inside a woman as a result.

98. Admit that you knew as of May of 1999 that it had been reported that the frayed edges of the TVT mesh could protrude through a woman's vaginal wall as described in ETH.MESH 02620914, attached hereto.

99. Admit that you knew as of May of 1999 that it had been reported that the frayed edges of the TVT mesh could protrude through a woman's vaginal wall and cause pain or discomfort to a woman.

100. Admit that you knew as of May of 1999 that it had been reported that the frayed edges of the TVT mesh could protrude through a woman's vaginal wall and cause pain or discomfort to a woman's sexual partner.

101. Admit that you knew that rough edges of the TVT mesh could cause pain for patients as indicated in ETH.MESH .01218019, attached hereto, by the end of 2006.

102. Admit that the TVT IFU has never stated to physicians that the frayed edges or rough edges of the TVT mesh could cause pain to a woman.

103. Admit that the TVT IFU has never stated to physicians that the frayed edges or rough edges of the TVT mesh could cause pain to a woman's sexual partner.

104. Admit that your patient brochures have never advised or informed women that the rough or frayed edges of the TVT mesh could cause pain following the TVT procedure.

105. Admit that you knew by the end of 2007 that an article in the peer reviewed literature reported that one of the primary problems with using the TVT is that the mesh easily deforms when tensioning under the urethra. (*See* ETH.MESH 00294195 attached hereto) .

106. Admit that you knew by the end of 2007 that the Moalli et al. study, published in the *International Urogynecology Journal* in 2007 compared TVT mesh to other types of meshes

in a study of elongation of the meshes and found that there was irreversible deformation of the TVT mesh with very little force and that the mesh easily elongates with very little tension.

107. Admit that you knew at the time the TVT was first marketed in the U.S. that the TVT mesh could become permanently deformed during insertion of the TVT mesh.

108. Admit that the IFU has never stated to physicians that the TVT mesh can become deformed with tension during placement.

109. Admit that you have known since the TVT was first marketed and sold in the U.S. that the scar tissue that develops around the mesh used in the TVT can cause the TVT mesh to contract following implantation in the human body.

110. Admit that you have known since at least November of 2002 that TVT mesh can contract following implantation in the human body as a result of the formation of scar tissue throughout or around the mesh as stated in ETH.MESH 03917375, attached hereto.

111. Admit that mesh contracture (mesh shortening due to scar tissue) is a complication of the TVT mesh that you have known about since the TVT was first marketed or sold in the U.S.

112. Admit that the first time you disclosed to patients in a patient brochure that mesh "contracture (mesh shortening due to scar tissue)" is a complication of the TVT mesh was in 2012.

113. Admit that the first time you disclosed to patients in a patient brochure that mesh "contracture (mesh shortening due to scar tissue)" is a complication of the TVT mesh was in 2012 even though you knew about that complication associated with the TVT for many years.

114. Admit that the first time you disclosed to patients in a patient brochure that mesh "contracture (mesh shortening due to scar tissue)" is a complication of the TVT mesh was in

2012 even though you knew about that complication associated with the TVT mesh for over ten years.

115. Admit that TVT mesh contracture (mesh shortening due to scar tissue) is associated with pelvic pain.

116. Admit that TVT mesh contracture (mesh shortening due to scar tissue) is associated with pain with intercourse.

117. Admit that you disclosed to patients in a 2012 TVT patient brochure that mesh “contracture (mesh shortening due to scar tissue)” can cause pelvic pain or pain with intercourse.

118. Admit that you have known that TVT mesh can contract due to scar tissue and lead to pelvic pain or pain with intercourse for more than five years.

119. Admit that you have known that TVT mesh can contract due to scar tissue and lead to pelvic pain or pain with intercourse for more than ten years.

120. Admit that the TVT IFU has never stated to physicians anything about TVT mesh contraction.

121. Admit that the TVT IFU has never stated to physicians that mesh contraction or mesh shrinkage following implantation of the TVT can cause chronic pain.

122. Admit that the TVT Patient Brochures have never specifically informed or advised patients that mesh contraction (mesh shortening due to scar tissue) can cause chronic pain.

123. Admit that you have approved and put in use more than 20 TVT patient brochures from 2000 until 2013.

124. Admit that the “product information” attached to the approved and in-use TVT patient brochures identified in the TVT/SUI Patient Brochures Index and Production Bates

Range Chart Produced to Plaintiffs in 08/26/13was not written in lay person language as recommended by the FDA in its Guidance on Medical Device Patient Labeling; Final Guidance for Industry and FDA Reviewers issued on April 19, 2001.

125. Admit that the first approved and in-use TVT patient brochure that included disclosure of the following risks associated with the TVT was the patient brochure approved for use on February 7, 2011,: nerve damage that mesh could become exposed into the vaginal canal, that mesh exposure can be associated with pain during intercourse for the patient and her partner, risks of developing urinary incontinence or difficulty urinating, and that exposure may require treatment, such as vaginal medication or removal of the exposed mesh in the operating room.

126. Admit that the first approved and in-use TVT patient brochure that included disclosure of the following risks associated with the TVT was the patient brochure approved for use on December 10, 2012,: pelvic pain, hemorrhage or hematoma, urinary tract infection, development of urinary incontinence, wound healing problems, fistula, injury to ureters, pelvic abscess formation, vaginal scarring or mesh contracture, infection, or inflammation.

127. Admit that you have known that the following risks are associated with the TVT since at least the year 2000: erosion, extrusion, exposure, pelvic pain, pain with intercourse, urinary tract infection, hematoma, hemorrhage, pelvic abscess formation, infection, inflammation, the development of urinary incontinence, damage to bowel, bladder, and nerves, wound healing problems, difficulty urinating, and that exposure of the mesh may require treatment including removal in the operating room.

128. Admit that the TVT IFU has never specifically stated that “dyspareunia” is an adverse reaction associated with the TVT.

129. Admit that the TVT IFU has never specifically stated that "wound healing problems" is an adverse reaction associated with the TVT.

130. Admit that the TVT IFU has never specifically stated that "rejection of the mesh" is an adverse reaction associated with the TVT.

131. Admit that some complications associated with the TVT can be permanent and life altering.

132. Admit that the TVT IFU has never stated to physicians that removal of the mesh might be necessary.

133. Admit that the TVT IFU has never stated to physicians that removal of the mesh might be difficult or impossible.

134. Admit that you have known since at least 2000 that placement of the TVT may result in incomplete or no relief from urinary incontinence.

135. Admit that the mesh used in the TVT can cause a chronic foreign body reaction.

136. Admit that the mesh used in TVT can cause chronic inflammation.

137. Admit that the TVT IFU has never stated to physicians that the TVT can cause a chronic foreign body reaction.

138. Admit that the TVT IFU has never stated to physicians that the mesh used in TVT can cause chronic inflammation.

139. Admit that the TVT Patient Brochures have never advised or informed patients that the mesh used in TVT can cause a chronic foreign body reaction.

140. Admit that the TVT Patient Brochures have never advised or informed patients that the mesh used in TVT can cause chronic inflammation.

141. Admit that the mesh in the TVT can cause severe inflammation in some women.

142. Admit that the mesh in the TVT can cause chronic inflammation in some women.

143. Admit that you have known since the TVT was first marketed and sold in the U.S. that TVT mesh can cause severe and chronic inflammation in some women.

144. Admit that the IFU has never stated to physicians that the mesh in the TVT can cause severe and chronic inflammation in some women.

145. Admit that a potential complication of the TVT is repeated occurrences of exposure of the mesh into the vagina.

146. Admit that the TVT Patient Brochures in existence prior to December of 2008 did not advise or inform patients of the risk of pain with intercourse following implantation of the TVT devices.

147. Admit that in December of 2008, Ethicon released a Patient Brochure that identified pain with intercourse as a risk of the TVT for the first time.

148. Admit that you knew at the time of the introduction of the TVT devices that pain with intercourse was a potential adverse reaction associated with use of the TVT.

149. Admit that chronic pain is a potential risk of the TVT procedure.

150. Admit that the TVT Patient Brochures in use prior to 2011 do not specifically advise or inform patients that there is a risk of mesh exposure requiring mesh removal in the operating room.

151. Admit that the TVT Patient Brochure in use starting in January of 2011 was the first Patient Brochure to warn of the risk of mesh exposure that may require mesh removal in the operating room.

152. Admit that the TVT patient brochures have never advised or informed patients specifically of the risk of the need for recurrent or multiple surgeries to treat mesh erosion or exposure into the vaginal canal.

153. Admit that you did not track when the TVT patient brochures were delivered to any individual physician's office.

154. Admit that you never instructed a physician to remove older versions of the TVT brochures from his or her office.

155. Admit that the TVT IFU has never included a statement warning or informing physicians that patients may need multiple surgeries to treat mesh erosion or exposure into the vaginal canal.

156. Admit that complications resulting from the TVT procedure can permanently impair a woman's ability to engage in comfortable sexual relations.

157. Admit that the TVT Patient Brochures do not advise or inform patients that the risk of pain with intercourse following the TVT implantation procedure can be permanent in some women.

158. Admit that Ethicon has known that pain with intercourse was a potential complication of the TVT procedure at all times while selling and marketing the TVT.

159. Admit that Ethicon has known that chronic pain is a potential complication of the TVT procedure at all times while selling and marketing the TVT.

160. Admit that the risk of erosion into the vagina following the TVT implantation procedure is a lifelong risk for patients.

161. Admit that Ethicon has known that the risk of erosion into the vagina following the TVT implantation procedure is a lifelong risk for patients at all times while selling and marketing the TVT in the U.S.

162. Admit that the TVT Patient Brochures do not advise or inform patients that the risk of erosions or exposures into the vaginal canal is a lifelong risk.

163. Admit that the TVT IFU has never stated to physicians that the risk of erosion of the mesh is a lifelong risk for patients.

164. Admit that the TVT IFU has never stated to physicians that TVT mesh is associated with excessive scarring around the mesh, scar plate formation, mesh encapsulation, and nerve entrapment.

165. Admit that it would be untrue for you to state to physicians that the mesh in the TVT does not degrade in a woman's body.

166. Admit that no testing was performed by J&J and Ethicon, or on its behalf, to measure or otherwise determine the potential for degradation of the TVT mesh prior to the filing of this civil action.

167. Admit that no testing was performed by you prior to the filing of this civil action, or on your behalf, to measure or otherwise determine the potential for particle loss of the TVT mesh used in the TVT.

168. Admit that no testing was performed by you prior to the filing of this civil action, or on your behalf, to measure or otherwise determine the safety or potential health consequences of the particle loss that occurs from the TVT.

169. Admit that the only study that was performed by you to analyze the degradation of its mesh was the 10-year Dog Study, Study No ERF-85219

170. Admit that the only study that was performed by you to analyze the degradation of its mesh was the 10-year Dog Study, Study No. ERF 85-21933.

171. Admit that the 10-year Dog Study No. ERF 85-219 was stopped after seven years.

172. Admit that the 10-year Dog Study No. ERF 85-219did not use the identical mesh used in the TVT products.

173. Admit that the 10-year Dog Study No. ERF 85-219used suture material only.

174. Admit that the 10-year Dog Study No. ERF 85-219 was comparing four sutures – Prolene, PVDF, Ethilon and Novafil.

175. Admit that at year seven of the 10-year Dog Study No. ERF 85-219, the Prolene* suture showed that the "degradation was still progressing after seven years".

176. Admit that at year seven of the 10-year Dog StudyNo. ERF 85-219, the PVDF suture did not show degradation.

177. Admit that you did not do any further testing of your Prolene* sutures after the 10-year Dog study No. ERF 85-219 was stopped in year seven.

178. Admit that you knew prior to the launch of your TVT products that the terms "high responder" and "low responder" referred to the fact that some women would have better post-surgical results than other women after implantation of the TVT products.

179. Admit that you have never performed studies regarding which women would have severe and life-altering complications as a result of implantation of the TVT products.

180. Admit that you never warned or advised doctors in the TVT IFU that some women could have severe, life-altering complications as a result of implantation of the TVT.

181. Admit that you never included in the TVT IFU a statement warning or informing physicians that you had not studied or determined which women might have severe, life-altering complications as a result of implantation of the TVT.

182. Admit that you never warned or notified women in your TVT patient brochures that some women could have severe, life-altering complications as a result of implantation of the TVT.

183. Admit that you had knowledge of the Sunoco Material Safety Data Sheet for Polypropylene Homopolymer, ETH.MESH. 02026591 attached hereto, since at least the end of 2005.

184. Admit that you have known since at least 2006 that polypropylene has been studied in laboratory rats by subcutaneous implantation of discs or powder, and that local sarcomas were induced at the implantation site in such study.

185. Admit that you have never informed or warned doctors in your TVT IFU that polypropylene has been tested in laboratory rats by subcutaneous implantation of discs or powder and that local sarcomas were induced at the implantation site in the test, as stated in the Sunoco Material Safety Data Sheet for Polypropylene Homopolymer, ETH.MESH. 02026591 attached hereto.

186. Admit that you have never informed doctors or patients about the results of the laboratory rat study that showed cancer at the implantation site of the polypropylene discs or powder, as stated in the Sunoco Material Safety Data Sheet for Polypropylene Homopolymer, ETH.MESH. 02026591 attached hereto.

187. Admit that you have never done any study or testing in humans or animals to determine if polypropylene or polypropylene mesh is associated with or capable of causing cancer.

188. Admit that by the year 2000 you were aware of the findings of the International Agency for Research on Cancer (IARC 1999) that polypropylene is possibly carcinogenic to humans.

189. Admit that from 1994-1998, Ethicon collaborated with Professors Klinge and Klosterhalfen in the development of Vypro.

190. Admit that in approximately 1998, Ethicon learned through its collaboration with Professors Klinge and Klosterhalfen during the development of Vypro, that heavyweight meshes with pore sizes of less than 1 mm in diameter in all directions increase the inflammatory and foreign body response compared to lighter weight meshes with pore sizes greater than 1 mm in diameter in all directions.

191. Admit that in approximately 1998, Ethicon learned through its collaboration with Professions Klinge and Klosterhalfen that small-pore mesh can become incorporated entirely in scar tissue, which bridges the whole pore diameter of less than 1 mm in diameter in all directions in scar tissue and can lead to the formation of a rigid scar plate and mesh encapsulation in scar tissue.

192. Admit that the body's reaction to heavyweight meshes with pore sizes less than 1 mm in diameter in all directions can result in inflammation and scar contraction around the mesh.

193. Admit that inflammatory reaction to heavyweight mesh can form a scar-plate around the mesh prosthetic that results in a firm and contracted mesh.

194. Admit that reducing the amount of foreign body material of heavyweight meshes can reduce the inflammatory response.

195. Admit that increasing the mesh pore size to greater than 1 mm in diameter in all directions can reduce the inflammatory response.

196. Admit that one of the reasons why you developed lighter weight, larger pore meshes in hernia and pelvic organ prolapse repair was because of your knowledge regarding the increased risk of inflammation and foreign body response associated with heavy weight, small pore meshes (meshes with a pore size of less than 1 mm in diameter in all directions).

197. Admit that one of the reasons why you began manufacturing hernia and pelvic organ prolapse repair meshes using Prolene* fibers thinner than the 6 mil Prolene* fibers used in TVT was because of your knowledge regarding the increased risk of inflammation and foreign body response associated with heavyweight, small pore meshes

198. Admit that one of the reasons why you developed meshes with larger pores than the TVT mesh to be used in hernia repairs and pelvic organ prolapse repairs was because of your knowledge regarding the increased risk of inflammation and foreign body response associated with heavyweight, small pore meshes.

199. Admit that your Ultrapro mesh used for hernia repair is a lightweight, large pore mesh as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto.

200. Admit that Gynemesh PS is a medium weight mesh, as defined by Cobb W, Kercher K, Heniford T. The Argument for Lightweight Polypropylene Mesh in Hernia Repair. Surgical Innovation. 2005; 12(1):T1-T7), with larger pores than the Prolene* mesh used in TVT.

201. Admit that you have known since the development of Vyprohat lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of inflammation.

202. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al.,Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of foreign body response.

203. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of fibrotic bridging.

204. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of scar plate formation.

205. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of mesh encapsulation in the scar.

206. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface

Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of mesh contraction or shrinkage.

207. Admit that you have known since the development of Vypro that lighter weight larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of patient complications.

208. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of nerve entrapment.

209. Admit that you have known since the development of Vypro that lighter weight larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease patients' risk of chronic pain.

210. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by, can decrease patients' risk of chronic pelvic pain.

211. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of erosion.

212. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface

Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease patients' risk of recurrence.

213. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of pelvic organ dysfunction (the loss of pelvic organ function).

214. Admit that you have known since the development of Vipro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease patients' risk of dyspareunia.

215. Admit that you have known since the development of Vypro that lighter weight, larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of mesh-related infections.

216. Admit that you have known since the development of Vypro that lighter weight larger pore meshes, as defined by Klinge et al., Impact of Polymer Pore Size on the Interface Scar Formation in a Rat Model, Journal of Surgical Research 103, 208-214 (2002) attached hereto, can decrease the risk of additional surgeries necessary to revise and/or remove the mesh.

217. Admit that under the ISO Elusion cytoxicity testing conducted by NAmSA in July of 1997, the final TVT device tested positive for severe cytotoxicity.

218. Admit that in the CE Mark Technical File (ETH.MESH.06851860) Ethicon acknowledged that the Prolene* mesh used in the TVT device has cytotoxic potential.

219. Admit that the TVT IFU has never stated to physicians that the TVT device tested positive by NAmSA for severe cytotoxicity in July of 1997.

220. Admit that the TVT IFU has never stated to physicians that the TVT device has cytotoxic potential.

221. Admit that the original device used by Medscand's Scandinavian Multicenter Study submitted with the 510(k) was different from the finished TVT device which tested severely cytotoxic by NAmSA in 1997 under the ISO Elusion test.

Dated: October 24, 2013

By: /s/Thomas P. Cartmell

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4836-9825-0774, v. 1

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

--	x	
IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	:	**CIVIL ACTION NO. 2:12-md-02327** **MDL No. 2327**
--	:	Judge Joseph R. Goodwin
This Document Applies To All Actions	:	
--	X	

PLAINTIFFS' CERTIFICATE OF SERVICE OF PLAINTIFFS' FIRST REQUESTS FOR ADMISSION TO DEFENDANTS

Plaintiffs hereby certify that on October 24, 2013, they served Plaintiffs' First Requests for Admission to Defendants via United States mail and electronic mail upon:

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4828-0977-9222, v. 1